

Human Health and Ecological Risk Assessment:

The Good, The Bad, and the New Stuff

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Episode 1:

Risk Assessment:

New Beginnings

Just a few weeks ago in an office not too far, far away, two **NAVFAC** Atlantic risk geeks wanted to bring a better understanding to the universe of RPMs that dread reading anything about risk assessments.

Objectives and Overview



- Learning objective: Know just enough about HHRA to be dangerous!
- Overview of HHRA Portion of Presentation
 - Site management
 - Site-specific assessments
 - Data analysis
 - This is not the target blood lead level you're looking for
 - Five Year Reviews
 - Transition to the dark side

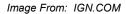
HHRA and **Managing Your Site**



- HHRA is not a "necessary evil"
 - CERCLA is a risk based program
 - The risk assessment should be written in such a way that it helps inform the decision of how a site should be managed
 - Bottom line should be clear and not
 - buried in pages and pages of text or

summarized as a table of all numbers

If you can't use the force, then use your human health risk assessment to help you manage your site.



Site-Specific Risk Assessments



- Make sure the HHRA is for this site
 - Target receptors and exposure parameters
 - Exposures must be reasonable for this site
 - Example: Excerpts from site description

No roads access the area. The site is comprised of a large, constructed sand and gravel pad surrounded and underlain by Arctic tundra. The only remaining features at the site are the gravel pad, two dilapidated gravel runways, two concrete foundations, and three capped landfills. Figure 2-2 depicts a map of the

The terrain is very flat with many thaw lakes and small wetlands, formed by ice wedges sinking or being pushed up by freeze-thaw cycles of the region. The plain has very cold average temperatures (-30°C to 8°C), strong and persistent winds, frequent cloud cover and/or fog, and approximately 30 cm to 75 cm of snowfall annually (URS Corporation, 2005). Temperatures are generally below freezing from mid-October through May, but warm during to the summer to an average 8°C in July (URS Corporation, 2005).

Site-Specific Risk Assessments



Example (con't)

Please fire me from this job!

Head, forearms, and hands

	Comme	rcial/Industr	ial Worker	Adult Construction Worker					
	Soil	Surface Water	Sediment	Soil	Surface Water	Groundwater			
Exposure Frequency (day/yr) (1)	200	200	200	200	20	200 1 Carcinogens: 25 year Noncarcinogens: 200 days			
Exposure Time (hours/day) (2)		1	1	3	137				
Exposure Duration (years or days) (1)	25 years	25 years	25 years	Carcinogens: 25 years Noncarcinogens: 200 days	Carcinogens: 25 years Noncarcinogens: 200 days				
Incidental Soil or Sediment Ingestion Rate (mg/day) (3)	50 (indoor worker) and 100 (outdoor worker)		50 (indoor worker) and 100 (outdoor worker)	330 -		170			
Subsistence Ingestion Rate (g/day) (4)	2	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	X-8	1, 4 0		948			
Skin Surface Area Exposed (cm²) (5)	3527	3527	3527	3527	3527	3527			

This is why the only important numbers in the HHRA are **not** the hazard indices (HIs) and cancer risks!

Data Analysis



- Data analysis ≠ Selection of chemicals of potential concern (COPCs)
 - RAGS Part D tables and ProUCL output can be your friends
 - Make sure figures are useful and help explain the data

Data Analysis – RAGS Part D Table 2



TABLE 2.2 OCCURRENCE, DISTRIBUTION AND SELECTION OF CHEMICALS OF POTENTIAL CONCERN CARR POINT - IR SITE 22

Scenario Timeframe: Current/Future

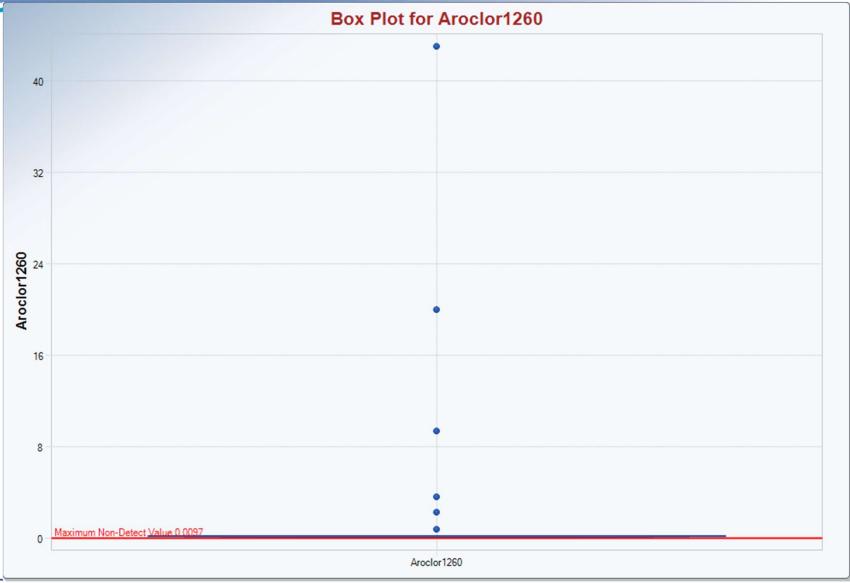
Medium: Soll

Exposure Medium: Surface/Subsurface Soil

Exposure Point	CAS Number	Chemical	Minimum Concentration (Qualifier) (1)	Maximum Concentration (Qualifier) (1)	Units	Location of Maximum Concentration	Detection Frequency	Range of Detection Limits	Concentration Used for Screening (2)	Value (3)	Screening Toxicity Value (N/C) (4)	Potential ARAR/TBC Value	Potential ARAR/TBC Source
Trespasser 8 19 9 9 8 110	206-44-0	FLUORANTHENE	0.002	39 J	mg/kg	CRP-SB05_0_1	61/110	0.0092 - 2	39	N/A	230 N	N/A	N/A
	86-73-7	FLUORENE	0.0037	0.52	mg/kg	CRP-SB321_4_6	23/110	0.009 - 2	0.52	NA	230 N	N/A	N/A
	193-39-5	INDENO(1,2,3-CD)PYRENE	0.0022	11 J	mg/kg	CRP-SB05_0_1	52/110	0.009 - 2	11	N/A	0.15 C	N/A	N/A
	91-20-3	NAPHTHALENE	0.003	0.35 J	mg/kg	CRP-SB05_0_1	22/110	0.009 - 2	0.35	N/A	3.8 C	N/A	N/A
	85-01-8	PHENANTHRENE	0.0019	17	mg/kg	CRP-SB321_4_6	61/110	0.009 - 2	17	N/A	170 N	N/A	N/A
	129-00-0	PYRENE PCBs	0.0022	38	mg/kg	CRP-\$B05_0_1	66/110	0.0092 - 2	38	N/A	170 N	N/A	N/A
	11097-69-1	AROCLOR-1254	0.074	2.9 J	mg/kg		4/106	0.0015 - 0.32	2.9	N/A	0.11 N	N/A	N/A
	11096-82-5	AROCI OR-1260	0.0046	45 .1	mg/kg	MW15_0_1 CRP-SB02_0_1	40 / 106	0.0015 - 0.02	45	N/A	024 C	NIA	N/A
	72-54-8	Pesticides 4,4-DDD	0.000061	0.11 J	mg/kg	CRP-SB305_4_6	12/106	0.0003 - 0.0036	0.11	N/A	2.2 C	N/A	N/A

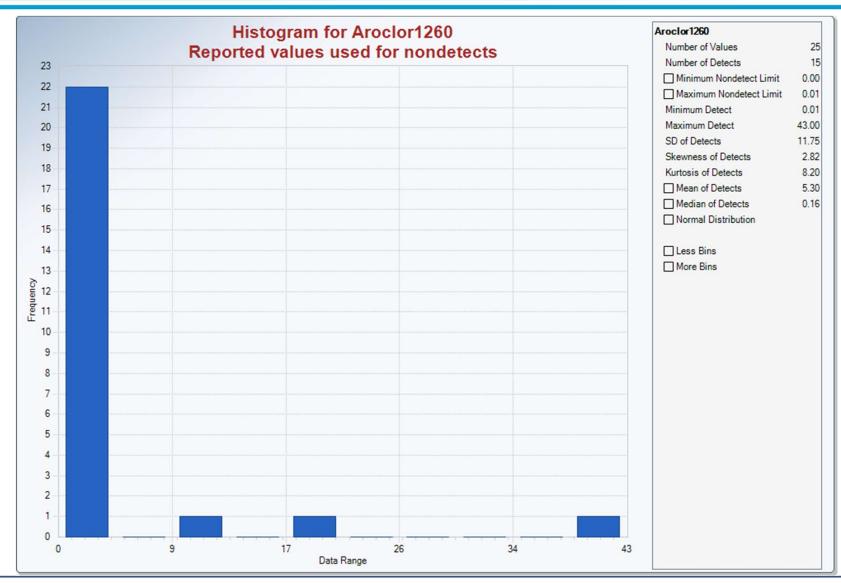
Data Analysis - ProUCL





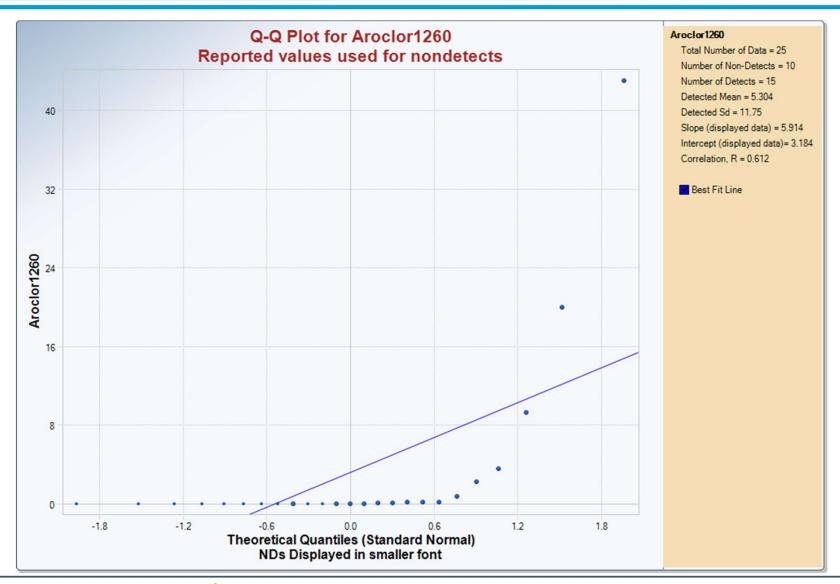
Data Analysis - ProUCL





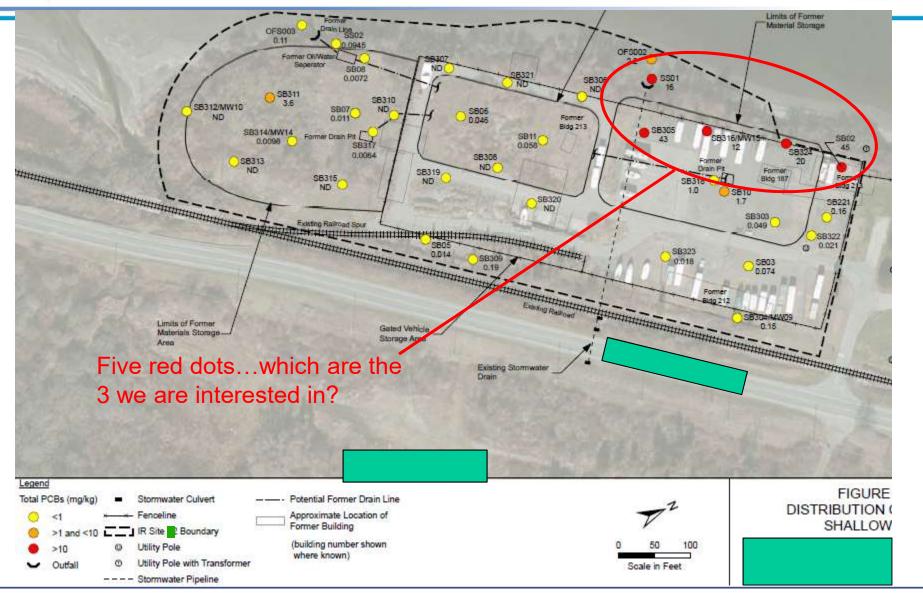
Data Analysis - ProUCL





Data Analysis – Figures







- What target blood lead level (BLL) should be used for site management?
 - 10 μg/dL vs. 5 μg/dL

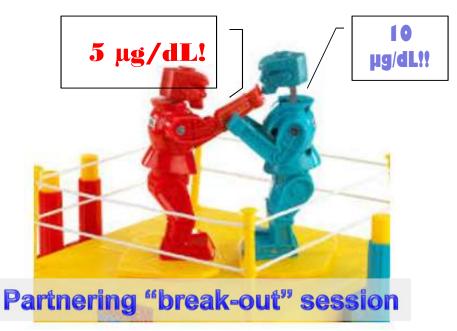




Image from Starloggers.com



- 1991: 10 µg/dL "level of concern" by CDC
- 1994: EPA OSWER Directive
 - Use the target BLL of 10 µg/dL and IEUBK model for CERCLA
 - Clarified, but reiterated in 1998 OSWER Directive
- 2012: 5 μg/dL "reference level" by CDC
 - No threshold where effects are not seen
- 2016: EPA memo "Updated Scientific Considerations for Lead in Soil Cleanups"
 - Still relies on 1994 OSWER Directive
 - Clarified, but reiterated in 1998



- 2016: EPA memo "Updated Scientific Considerations for Lead in Soil Cleanups"
 - Still relies on 1994 OSWER Directive
 - Still use IEUBK; on a site-specific basis parameters can be varied
 - "Consistent with existing policy, soils screening levels are generally not used as default preliminary remediation goals (PRGs) and cleanup levels."
 - Evaluate site-specific bioavailability
 - Consider the "Role of Background in the CERCLA Cleanup Program" OSWER Directive
 - NOTE: alternate target BLLs are not in the main text; they appear in a footnote and do not come along with recommendations to use them...merely summarizing current research findings



 2016: EPA memo "Updated Scientific Considerations for Lead in Soil Cleanups"

 $^{^1}$ The current scientific literature on lead toxicology and epidemiology provides evidence that adverse health effects are associated with blood lead levels (BLLs) less than 10 μg/dL. For example, EPA's Office of Research and Development reviewed the health effects evidence for lead in the 2013 Integrated Science Assessment for Lead (ISA for Lead) and found that several studies have observed "clear evidence of cognitive function decrements (as measured by Full Scale IQ, academic performance, and executive function) in young children (4 to 11 years old) with mean or group blood Pb levels between 2 and 8 μg/dL (measured at various lifestages and time periods)." In addition, the National Toxicology Program's (2012) Monograph on Health Effects of Low-Level Lead found sufficient evidence of delayed puberty, reduced post-natal growth, and decreased hearing for children at BLLs below 10 μg/dL and adverse effects on academic achievement, IQ, other cognitive measures, attention-related behaviors, and problem behaviors at BLLs below 5 μg/dL

Five Year Reviews



Risk language is very specific

Risk assessor does not have to write the text, but should review it!

Changes in Toxicity, Risk Assessment Methods, and Cleanup Levels our.

- Waste remains onsite beneath a soil cover. A remedy will be required a long as wastes remain in place.
- Changes in toxicity, risk assessment, and cleanup levels have occurred since ROD issuance in 1998. Risk was estimated for the future residential scenario based on beryllium, based on a single sample location. The exposure point concentration was 0.239 mg/kg. To evaluate changes in risk, the exposure point concentration was compared with the current U.S. FPA Residential Residential Screening Level (cancer risk 1E-06 and hazard index of 1 May 2017) for beryllium is 160 mg/kg. Similarly, the current FDEP Residential Soil Cleanup Target Level for beryllium (which is bar on the same cancer risk/hazard index) is 120 mg/kg. Both screening values ref the changes in toxicity and risk assessment methods, as they are developed us exposure-based models. Consequently, residual risk in soil at OU 1 is assumed be negligible.

I'm fluent in 6,000,000 forms of communication...but risk assessment isn't one of them. as

KNOWLEDGE CHECK



- Risk assessors know more about risk assessment than I do so I shouldn't question the:
 - **Exposure factors used?**
 - True or False
 - Conclusions in the risk assessment even though I can't really find them?
 - True or False
- As an RPM I can tell quite a bit about my site by looking at those annoying RAGS Part D tables and ProUCL output graphs.
 - **○True or False**
- Risk assessors do not need to work on Five Year Reviews.
 - **○True or False**



Transition to the Dark Side



Picture from www.nerdist .com adapted for illustration

Objectives and Overview



- Theme Revisiting the ERA and its Black Box Perception
- Overview of ERA Portion of Presentation
 - Why does ERA have an aura of being a black box science?
 - Review the ERA Process
 - ERA Planning Tips
 - Implementing the ERA
 - Coordinating the ERA with Other RI and FS Items
 - Nature and Extent
 - Information to support the evaluation of alternatives in the FS
 - Takeaways



Recovered After Decades Lost will the Secrets of Mystical ERA Black Box be Revealed??????

The Aura of the ERA Black Box



I am looking

for the ERA Black Box

- The Ecological Risk Assessment process can be viewed with skepticism, confusion, and uncertainty
 - Perceptions can ultimately skew realities but ≠ them
 - Perceptions can lead to too much reliance on the "ERA Experts" to plan and complete the risk assessment in the absence of keeping long-term remediation goals in mind.
 - "You're the expert, so I'll rely on what you recommend and say."
 - Uncertainty and differing opinions can definitely lead to confusion
 - Note: This is also present in other aspects of investigation and in human health risk assessment
- Bottom line you don't need to be an explorer or treasure hunter to open the ERA Black Box, just be patient, push your consultant, and seek clarity





Image from www. cinemablend.com

Refresher on ERA Process



- The USEPA and the Navy both have policy and guidance on completing ERAs under CERCLA
- CNO issued ERA Policy in 1999 that documented the anticipated flow and steps within the CERCLA Process
 - -Flow charts are easy...implementation is often the issue.
- Timely Plug Moment for more fun with eco risk think about attending the CECOS ERA Course in Norfolk, June 2018

Navy Ecological Risk Assessment Tiered Approach Tier 1. Screening Risk Assessment (SRA): Identify pathways and compare exposure point concentrations to bench marks. Step 1: Site visit; Pathway Identification/Problem Formulation; Step 2: Exposure Estimate; Risk Calculation (SMDP) 1 Exit Criteria for the Screening Risk Assessment: Decision for exiting or continuing the ecological risk assessment. Site passes screening risk assessment: A determination is made that the site poses acceptable risk and shall be closed out for ecological concerns. 2) Site falls screening risk assessment: The site must have both complete pathway and unacceptable risk. As a result the site will either have an interim RPM Input and Risk Management Consideration deanup or moves to the second tier. Tier 2. Baseline Ecological Risk Assessment (BERA): Exit Criteria Step 3a Refinement Detailed assessment of exposure and hazard to "assessment 1) If re-evaluation of the conservative endpoints" (ecological qualities to be protected). Develop site exposure assumptions (SRA) support specific values that are protective of the environment. an acceptable risk determination then Step 3a: Refinement of Conservative Exposure Assumptions² the site exits the ecological risk (SRA)---- Proceed to Exit Criteria for Step 3a assessment process. Step 3b: Problem Formulation - Toxicity Evaluation; 2) If re-evaluation of the conservative Assessment Endpoints; Conceptual Model; exposure assumptions (SRA) do not Risk Hypothesis (SMDP) support an acceptable risk Step 4: Study Design/DQO - Lines of Evidence; Measurement Endpoints; Work Plan and Sampling & Analysis Plan (SMDP) determination then the site continues in the Baseline Ecological Risk Assessment process. Proceed to Step 5: Verification of Field Sampling Design (SMDP) Step 3b Step 6: Site Investigation and Data Analysis [SMDP] Step 7: Risk Characterization Proceed to Exit Criteria for BERA Exit Criteria Baseline Risk Assessment 1) If the site poses acceptable risk then no further evaluation and no remediation from an ecological perspective is warranted. 2) If the site poses unacceptable ecological risk and additional evaluation in the form of remedy development and evaluation is appropriate, proceed to Tier 3. Evaluation of Remedial Alternative (RAGs C) a. Develop site specific risk based cleanup values. b. Qualitatively evaluate risk posed to the environment by implementation of each alternative (short term) impacts and estimate risk reduction provided by each (long-term) impacts; provide quantitative evaluation where appropriate. Weigh alternative using the remaining CERCLA 9 Evaluation Criteria. Plan for monitoring and site doseout. Notes: 1) See EPA's 8 Steps ERA Process for requirements for each Scientific Management Decision Point (SMDP). 2) Refinement includes but is not limited to background, bioavailability, detection frequency. Etc. 3) Risk Management is incorporated throughout the tiered approach. Figure 1 CNO. 1999

ERA Planning Tips



So little time, too many tips

–A Couple Good Ones:

- A consultant's risk assessor should never complete the ERA work plan without seeing the site first to actually evaluate the habitat present to select the appropriate receptors to evaluate in the Baseline Ecological Risk Assessment (BERA)
- Have an idea of concentration gradient or patterns before performing toxicity or bioaccumulation testing.
 - Maximize your chance for good dose response range and developing a site-specific BAF/BSAF for food web modeling
- Select species for food web modeling that make sense for your site.
- Strive to include reference locations (not location) in toxicity testing.
 - -Controls are for assessing test success, reference locations are to assess natural variability away from site contamination.
- Consider requesting the lab to monitor more frequently for confounding factors (e.g., ammonia) that themselves can cause toxicity
- Last but not least.....DQOs, DQOs in ERA Work Plan
 - Negotiations can be extremely painful, but document how data will be assessed and used to complete the interpretation of findings in the ERA portion of the RI.

Implementing the ERA



- Now you are going to the field to complete ERA field activities...nothing could possibly go wrong???
- Questions for implementation of ERA field work
 - -What's the weather forecast and will it hinder collection?
 - -What are the physical contingencies for sample collection if conditions weren't as expected?
 - -What are the biological contingencies for sample collection if target species for tissue samples are not available in the field?
 - —Is the lab performing toxicity/bioaccumulation testing ready to perform tests upon receipt?
 - -What are the communication pathways from the field crew to the consultant's PM and lead risk assessor, as well as the Navy RPM, to make intelligent changes in the field?
 - –Are the field crew experienced in collecting ERA samples?
 - -What field notes, including qualitative but scientific information, is the field crew planning to take?

Coordinating the ERA with Other RI and FS Items



- You are already out in the field to collect ERA data. What other sampling and information can be gathered to assess F&T, nature and extent, or evaluate potential alternatives in the FS?
 - —Is monitored natural recovery a potential alternative for your sediment site?
 - -Can additional sediment or soil samples be collected and held for analysis later to provide better nature and extent information to calculate removal volumes or treatment areas in FS?
 - Know your holding times
 - —Is potential discharge of contaminated groundwater to a water body a concern, and can I characterize the potential pathway while in the field?
 - -What hydrodynamic information can I collect in a water body to assist in assessing potential remedial alternatives?
 - -Are there areas where higher bioaccumulation is likely taking place vs others so that risk reduction and management decisions can be made with supporting information?

CSM for Thought in Big Picture



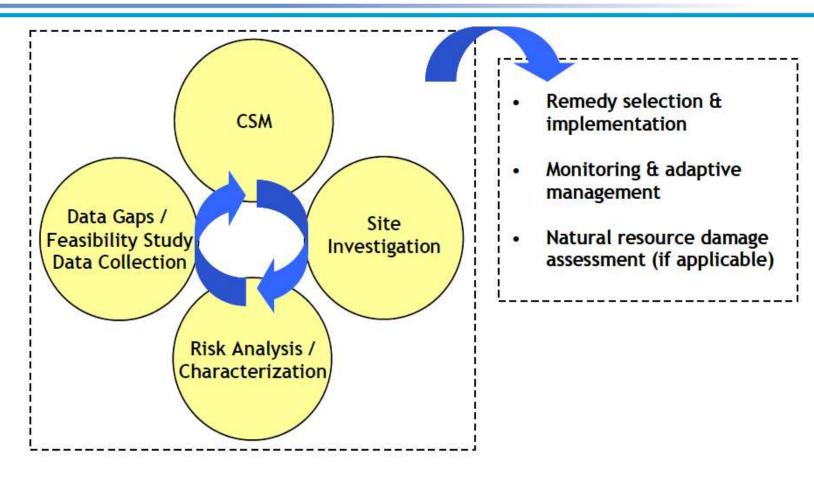


FIGURE 1-1. Conceptual site model as the basis for developing a remedial strategy.

Figure from Technical Guide for Monitored Natural Recovery at Contaminated Sediment Sites (ESTCP, 2009)

KNOWLEDGE CHECK



- When planning an ERA during the RI, only field work contributing to the risk assessment should be considered?
 - -True or False
- Communication pathways between the consultant and the Navy's RPM, and their technical support, is important for field work performed to support the ERA?
 - -True or False
- •My site includes a forested wetland with no consistent standing water, and my consultant is proposing a picivorous bird as a higher level receptor for the ERA. What should I do?
 - a) Question my consultant's choice of the receptor based on my understanding of the site.
 - b) Support the selection of the Great Blue Heron as an appropriate receptor to evaluate for my site.
 - c) Ask my consultant if their eco-risk assessor ever visited the site.
 - d) A & C

Take Away Messages



- •Planning and completing an ERA can be a difficult road, but how many things are simple in the environmental world?
 - -Not like we are searching for the Holy Grail of ERA knowledge
- Planning for an ERA is just as important as completing it
 - -Push your consultants to properly plan and layout the framework for interpretation of data...we don't just pay them to do, we pay them to think too!!!!
- Plan for and use your ERA findings to develop preliminary remediation goals to carry into your FS
 - -Your final remediation goals for selected remedy should be balanced with risk management
- •When in doubt, common sense comes in very handy when asking questions and pushing for clarity with regulators and consultants.



I heard the

Picture from www.fanpop.com adapted for illustration

Contacts and Questions



Points of Contact – NAVFAC ATLANTIC RISK TEAM

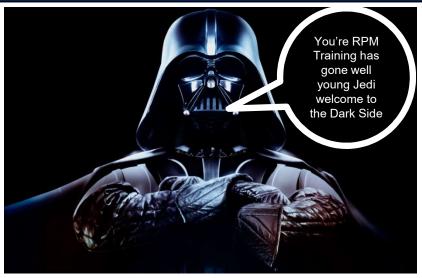
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Questions?



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